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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10419]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: New collection (request for a new OMB control number); Title of Information Collection: Transparency Reports and Reporting of Physician Ownership or Investment Interests; Use:

Reports of Payments or Other Transfers of Value to Covered Recipients

The regulations at 42 CFR 403.904 require direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient, and that direct and indirect

payments or other transfers of value provided to a third party at the request of (or designated by) the applicable manufacturer on behalf of a covered recipient, be reported by the applicable manufacturer to CMS on an annual basis.

Reports of Physician Ownership and Investment Interests

Under §403.906, each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.

Data Collection

The data templates will provide detailed information about the data to be collected including the data element name, format, allowable values, required versus optional fields, and other associated rules intended to aid the applicable manufacturers and applicable group purchasing organizations as they prepare for and participate in data collection. Applicable manufacturers and applicable GPOs will engage in data collection external to CMS within their own systems or tracking tools. If we intend to make changes to the data templates, we will provide them at least 90 days prior to first day of data collection for the next reporting year. In providing revised templates, we will also comply with the requirements of the Paperwork Reduction Act to seek public comments on the proposed changes to the information collections, as required by law. This will allow applicable manufacturers and applicable GPOs to make any necessary changes to prepare for the next reporting year. This is the same time as the date by which we will publish the list of teaching hospitals.

Data Submission

Section 403.908 requires that reports must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year. Additionally, applicable manufacturers and applicable group purchasing organizations may submit an entirely optional assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.

Dispute Resolution and Corrections

There are several situations which may necessitate that data previously submitted be updated. These cases include corrections based on disputes, or corrections known by the applicable manufacturer or applicable GPO through another mechanism. For example, if an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, under §703.908(h), applicable manufacturers and applicable GPOs must notify CMS immediately upon discovering errors or omissions in their reports and must submit corrected information to CMS immediately upon confirmation of the error or omission. CMS will update the website at least once annually with corrected information. Form Number: CMS-10461 (OCN: 0938-New). Frequency: Annual; Affected Public: Private Sector (business or other for-profit and not-for-profit institutions); Number of Respondents: 396,414. Total Annual Responses: 396,414. Total Annual Hours: 13,327,065. (For policy questions regarding this collection contact Doug Brown at 410-786-0028. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on June 3, 2013.

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-6974

E-mail: OIRA_submission@omb.eop.gov.

Dated: May 1, 2013

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

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